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The 2017 European Society of Coloproctology (ESCP) collaborating group; Pinkney, Thomas

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Evaluating the incidence of pathological complete response in current international rectal cancer practice: the barriers to widespread safe deferral of surgery

The 2017 European Society of Coloproctology (ESCP) collaborating group*

**Collaborating authors listed at end of manuscript*

Corresponding author:

Mr Nick J Battersby

European Society of Coloproctology (ESCP) Cohort Studies Committee

Department of Colorectal Surgery

Salisbury NHS Foundation Trust

Salisbury

SP2 8BJ

~~European Society of Coloproctology (ESCP) Cohort Studies Committee~~

~~Pelican Cancer Foundation~~

~~Dinwoodie Drive~~

~~Basingstoke~~

~~RG24 9NN~~

United Kingdom

Email: nickbattersby@nhs.net

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Abstract

Introduction: The mainstay of management for locally advanced rectal cancer is chemoradiotherapy followed by surgical resection. Following chemoradiotherapy, a complete response may be detected clinically and radiologically (cCR) prior to surgery or pathologically after surgery (pCR). We aim to report the overall complete pCR rate and the reliability of detecting a cCR by conventional pre-operative imaging.

Methods: A pre-planned analysis of the European Society of Coloproctology (ESCP) 2017 audit was performed. Patients treated by elective rectal resection were included. A pCR was defined as a ypT0 N0 EMVI negative primary tumour; a partial response represented any regression from baseline staging following chemoradiotherapy. The primary endpoint was the pCR rate. The secondary endpoint was agreement between post-treatment MRI restaging (yMRI) and final pathological staging.

Results: Of 2572 patients undergoing rectal cancer surgery in 277 participating centres across 44 countries, 673 (26.2%) underwent chemoradiotherapy and surgery. The pCR rate was 10.3% (67/649), with a partial response in 35.9% (233/649) patients. Comparison of AJCC stage determined by post-treatment yMRI with final pathology showed understaging in 13% (55/429) and overstaging in 34% (148/429). Agreement between yMRI and final pathology for T-stage, N-stage, or AJCC status were each graded as 'fair' only (n=429, Kappa 0.25, 0.26 and 0.35 respectively).

Conclusion: The reported pCR rate of 10% highlights the potential for non-operative management in selected cases. The limited strength of agreement between basic conventional post-chemoradiotherapy imaging assessment techniques and pathology suggest alternative markers of response should be considered, in the context of controlled clinical trials.

What this study adds

This paper highlights thea potential for selective non-operative management of rectal cancer with long-course chemoradiotherapy, highlighting a complete pathological response rate of 10.3% in an international audit. There was limited agreement between basic conventional post-chemoradiotherapy imaging and pathological staging, demonstrating a need for more sensitive markers of treatment response.

Introduction

Approximately 450 000 rectal cancers are diagnosed worldwide annually [1]. In developed countries, in which 55% of these diagnoses are made, 45-55% of electively managed patients will receive chemoradiotherapy prior to the cancer resection [2]. The surgical resection, performed according to the principles of total mesorectal excision (TME), is widely regarded as the mainstay of curative treatment for resectable rectal cancer [3]. However, rectal cancer resections have significant morbidity along with a 90-day mortality of approximately 4% - 5% [2, 4]. Furthermore, the long-term consequences of treatment of pre-operative radiotherapy and surgery can profoundly impair quality of life, this may be attributed to bowel dysfunction following a restorative procedure [5, 6], living with the challenges and complications of a permanent stoma [7], or genitourinary side effects of treatment [8].

Over the past decade there has been increasing interest in avoiding the consequences of a TME procedure through organ preserving approaches [9, 10]. This is on the proviso that equivalent or favourable oncological outcomes can be achieved with a lower overall morbidity. One approach has been to consider deferral of surgery, whereby patients who have responded favourably to pre-operative chemoradiotherapy do not undergo surgery if there is no evidence of detectable tumour by clinical, endoscopic and radiological surveillance. These patients are diagnosed with a clinical complete response (cCR), this approach is also termed “Watch and Wait” or ‘Non-Operative Management [11, 12].

The original Watch and Wait concept was based on the observation of no residual tumour cells (a pathological complete response (pCR)) in up to 26.8% of rectal cancer specimens following chemoradiotherapy [10]. Furthermore, with optimal follow-up, selected patients who participate in these programmes were reported to have favourable oncological outcomes compared with patients who underwent surgery, with 5-year disease-free and overall survival exceeding 90%

[10]. Deferral of surgery is increasingly reported as a feasible approach for rectal cancer management, with acceptable detection rates of regrowth and safe surgical salvage [13, 14]. A meta-analysis of 17 studies, from centres with established surveillance protocols for deferral of surgery, reported a clinical complete response rate (cCR) of 22.4% (95% CI:14.3–31.8) [15]. However most of these centres pursue strategies thought to enhance the likelihood of a favourable response, including consolidation or induction chemotherapy sensitizing regimes [16] radiotherapy dose escalation of up to 66Gy [17] and offering chemoradiotherapy to smaller tumours (over 25% of the tumours in the meta-analysis were cT2 or less) [15].

The aim of this study was to record the complete pathological response rate reported in a 'real world' setting in order to determine the potential for widespread uptake of non-operative rectal cancer management. We also aimed to determine whether conventional radiological assessment of response to chemoradiotherapy is sufficiently reliable to feasibly consider generalised implementation of non-operative management in current clinical practice.

Methods

Protocol

This prospective, observational, multi-centre study was conducted in line with a pre-specified protocol (http://www.escp.eu.com/research/cohort-studies). An external pilot of the protocol and data capture system was conducted in five international centres prior to launch, allowing refinement of the study tool and delivery. This data was not included within the main study analysis.

Centre eligibility

Any unit performing gastrointestinal surgery was eligible to register to enter patients into the study. No minimum case volume, or centre-specific limitations were applied. The study protocol was disseminated to registered members European Society of Coloproctology (ESCP), and through national surgical or colorectal societies. Units recruiting patients to rectal cancer trials were still eligible to participate in the study.

Patient eligibility

Adult patients (≥16 years) undergoing elective resection for rectal cancer treated with long-course pre-operative chemoradiotherapy, with or without metastatic disease, were extracted from the main audit database. A rectal cancer was defined as an adenocarcinoma 0-15cm from the anal verge on rigid sigmoidoscopy or MRI. Concomitant chemoradiotherapy was a mandatory inclusion criteria, however the dose of chemotherapy and the delivery of long-course radiotherapy was administered to according to unit and clinician preference. Patients undergoing palliative pre-operative therapy, chemotherapy alone or short course radiotherapy were excluded.

Data capture

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Consecutive sampling was performed for eligible patients over an 8-week study period in each included centre. Local investigators commenced data collection on any date between the 1 February 2017 and 15 March 2017, with the last eligible patient being enrolled on 10 May 2017. Small teams of up to five surgeons or surgical trainees worked together to collect prospective data on all eligible patients at each centre. Quality assurance was provided by at least one consultant or attending-level surgeon. Data was recorded contemporaneously and stored on a secure, user-encrypted online platform (REDCap) without using patient identifiable information. Centres were asked to validate that all eligible patients during the study period had been entered, and to attain >95% completeness of data field entry prior to final submission.

Demographic data including Age, Gender, American Society of Anaesthesiologists (ASA) classification grade, smoking history, body mass index, cardiovascular disease, indication for surgery and disease location. The index operation, operative steps, approach, duration and morbidity were recorded. Tumour staging information (T-stage, N-stage, extramural vascular invasion), recorded at three different timepoints, were available: 1. Baseline pre-neoadjuvant treatment MRI staging; 2. Post-treatment MRI staging; 3. Post-treatment pathological staging. Staging was summarised according to IUCC/AJCC TNM 7 system [18]. The MRI Rectum was performed according to individual unit protocol. An MRI for baseline staging was mandatory for all rectal cancers included in the study, the post treatment MRI was encouraged but was not compulsory. A complete pathological response (pCR) has been defined previously as ypT0,N0 [19], our definition also required the ypEMVI status to be negative. Tumor regression was staged into three categories: a complete pathological response (no visible cancer cells), a partial response (regression from baseline MRI to pathology for one or more of T stage, N stage, EMVI status), and no change/progression from the baseline MRI staging. The circumferential rectal margin (CRM) was regarded as involved if the microscopic tumor

extension reached ≤1mm from the margin. Central quality control of surgical specimens by pathologic examination was not performed.

Outcome measures

The primary outcome measure was the rate of complete pathological response. The secondary outcome measure was the concordance of the TNM-based post-treatment MRI assessment and post-treatment pathological staging for T stage, N stage and overall AJCC TNM grade, assessed using Kappa agreement and the Intraclass Correlation Coefficient.

Statistical analysis

This report has been prepared in accordance to guidelines set by the STROBE (strengthening the reporting of observational studies in epidemiology) statement for observational studies [20]. Patient, disease and operative characteristics were compared using descriptive analysis and tests of normality were used to guide analysis. Chi-squared test was used for categorical data, Student's t-test for normally distributed continuous data and Mann-Whitney U test for non-parametric data. To explore associations between T-stage, nodal status, EMVI status and tumour height with pathological complete response univariable logistic regression models were fitted, described as odds ratios with 95% confidence intervals.

The reliability of post-treatment MRI restaging to assess response to neoadjuvant therapy was assessed by the Kappa agreement between the post-treatment MRI and pathology T-, N- and AJCC-staging [21]. A Kappa value of <0.20 was interpreted as 'Poor', 0.21-0.40 as 'Fair', 0.41-0.60 as 'Moderate', 0.61-0.80 as 'Good', and 0.81-1.00 as 'Very good'. An estimate of the Intraclass Correlation Coefficient was also reported, with 95% exact confidence intervals (95% CI) derived using the variance components from a one-way ANOVA [22, 23]. Data analysis was undertaken using R Studio V3.1.1 (R Foundation, Boston, USA).

Ethical approval

All participating centres were responsible for compliance to local approval requirements for ethics approval or indemnity as required. In the UK, the National Research Ethics Service tool recommended that this project was not classified as research, and the protocol was registered as clinical audit in all participating centres.

Results

Figure 1 shows inclusion of patients within this study. A total of 2572 patients underwent surgery for rectal cancer in 277 participating centres across 44 countries. Of these , 673 (26.2%) underwent CRT and TME surgery. Twenty four patients were excluded due to missing MRI or pathology staging. The median (IQR) age of the remaining 649 patients was 65 years (56-71 years). 35% (229/649) were female.

pCR was reported in 10.3% (67/649) patients. An overall partial response occurred in 35.9% (233/649), with T stage regression in 42.8% (278/649), N stage regression in 71.6% of those with baseline node positivity (111/155), and EMVI regression in 82.5% with baseline mrEMVI positivity (33/40). No regression occurred in 53.8% (349/649) patients. Treatment failure with progression of T-staging was seen in 9.4% (53/562), N-staging in 8.9% (52/583) and EMVI-status in 17.6% (99/561).

Demographic and operative data are compared according to tumour response in Table 1. Overall the mean (SD) tumour height was 4.1cm [1.9], whereas the pCR group were significantly closer to the anal verge (mean (SD) 3.2cm [1.7], $p<0.007$). Patients with a pCR were more likely to undergo a restorative resection 73.1% ($p=0.004$) and a significantly higher proportion of robotic cases were performed on patients with a pCR (27%[13/48], $p<0.001$) compared with 11.4% [38/333] and 6.0% [16/268] for laparoscopic and open approaches, respectively. Response was not influenced by age, gender and patient fitness in this series. The degree of regression did not influence Clavien Dindo reported complication rates.

Baseline MRI staging (n=649), post-CRT MRI staging (n=429), and pathological staging are compared against tumour response in Table 2. A post-treatment MRI was performed in 66.1% (429/649) of patients. According to the baseline MRI over 70% of tumours were T3 in all

response groups, only 4.5% of pCR tumours were mrT4 and the highest proportion of T4 tumours were in the partial response group 23.6% (55/233). mrT1 were reported in 8 (1.2%) cases, these were mrEMVI or mrN2 +ve tumours and all patients were non-responders. Following CRT, ymrT1 was reported in 7.7% overall and in 20% of pCR group. Figure 2 displays response rates by tumour height and pre-treatment MRI T-stage. Complete response was more common in T1/T2 tumours than T3/T4 tumours (14.5% versus 9.7%), although this association was non-significant (T3/T4; OR: 0.64, 0.34-1.30, p=0.19). Despite trends towards a higher pCR rate in low or middle rectal disease, neither tumour height (Low rectum; OR: 1.82, 0.76−5.43, p=0.22, Middle rectum; OR: 1.64, 0.65−5.02, p=0.33) or EMVI status (EMVI positive; OR: 1.26, 0.42-3.07, p=0.64) were significantly associated with complete response. Node positivity at baseline was significantly associated with a lower rate of pCR (OR: 0.40, 0.17-0.81, p=0.02).

The pathology data is also summarised in Table 2. There was no tumour in the pCR group and therefore the grade of differentiation could not be determined, however there was no difference in the tumour grade for partial and non-responders. Non-responders were significantly more likely than partial responders to be ypEMVI positive (12.9% [30/233] v 24.4% [85/349], p<0.001). The overall pCRM rate was 6.2% [40/649].

The post-CRT MRI staging (n=429) is compared with pathology staging in Table 3. Overall understaging occurred in 14% (61/429) and 12.8% (55/429) of ypT stage and ypAJCC grade cancers respectively. Overstaging was reported in 35% (151/429) of ypT staging and 34% (148/429) of ypAJCC grading. Table 4 shows that the agreement between the post-treatment MRI and Pathology was graded ‘fair’ for T stage, N stage and AJCC status (Kappa 0.25, 0.26 and 0.35 respectively).

Discussion

This large, prospective international audit identified a pCR rate of 10.3% for patients with rectal cancer treated with preoperative chemoradiotherapy. This data was simultaneously collected from 262 units over a period of six weeks. It provides a unique and truly generalised 'snapshot' of the pathological response rate in current practice. Many regard a pathological response as a mixed blessing; on the one hand this reflects a favourable prognosis but on the other it may indicate an unnecessary operation with the sequelae that can follow. Consequently, there is increasing interest in trying to identify a pCR after chemoradiotherapy on clinical and radiological grounds rather than by pathological assessment. However, this 'real-world' MRI staging data gives us an indication that if current basic staging tools are used in isolation, they will be inadequate for accurately identifying and safely monitoring deferral of surgery patients.

The pCR rate reported in this study is consistent with rates in large trials that used single agent concomitant chemotherapy and a radiotherapy dose of ≥45Gy. The FFCD 9203, EORTC 22921 and the German Rectal Cancer Study (CAO/ARO/AIO-94) trials have been described extensively elsewhere they recruited cT3 or resectable cT4M0 adenocarcinoma of the rectum, located within 15cm, 15cm and 16cm of the anal verge respectively [24-26]. These trials reported pCR rates with pre-operative CRT of 11.4%, 14% and 8% respectively [24-26]. One review of phase II and III studies identified pCR rates ranging from 0-67% with an overall pCR rate of 13.5% [27].

This current study identified that a pCR was associated with a lower tumour height. This finding has been reported previously and authors postulate that lower tumours are fixed by the pelvic floor muscles allowing radiotherapy to be delivered more consistently which allows for a favourable response rate [28]. A significantly higher proportion of patients in the pCR group had a node negative tumour at baseline. As authors have previously discussed, this may indicate

that earlier stage tumours are more likely to produce a complete clinical response or this may reflect a more biiologically indolent tumour that is more likely to respond favourably to treatment [15,28-29]. The size of the tumour may also influence complete response rates [29], however in this study tumours were predominately mrT3 and the MRI baseline staging suggested CRT was given in order to downstage locally advanced tumours rather than to achieve a complete response in early stage tumours.

Other factors previously shown to be associated with an increased response rate include dual concomitant chemotherapy [27], induction chemotherapy [30], consolidation chemotherapy [31, 32], allowing time for regression between CRT and surgery [33], and intensified pre-operative radiotherapy [17]. The pathological assessment can also influence the pCR rate, and a thorough pathologist is less likely to identify a pCR. However recent guidelines for assessing post-CRT rectal cancer specimens provide recommendations on the number of levels that should be cut from each tumour block and these are likely to standardise the pathological assessment of response [34].

Enhancing the response to CRT and achieving a pCR is an encouraging outcome and many patients with a pCR will be reassured by the absence of a cancer. The long-term outcomes are highly favourable; the German Rectal Cancer trial reported a 10 year DFS of 89.5% a pCR, compared with 63% for poor responders (p=0.008) [35]. On the other hand this represents a missed opportunity for organ preservation. In selected patients it is possible to avoid surgery. Thus much of the morbidity may be prevented along with the reported 90-day post-operative mortality of 4% - 5% [4]. Deferral of surgery has now been reported for 867 patients from 23 studies [13]. In highly selected cases, motivated centers with established protocols for deferral of surgery, report no significant difference between 'deferral of surgery' versus a clinical

complete response in terms of non-regrowth recurrence (RR 0.58, 95% CI 0.18-1.90), disease-free survival (HR 0.56, 95% CI 0.20-1.60), or overall survival (HR 3.91, 95% CI 0.57-26.72) [13].

The challenge that currently prevents widespread uptake of 'deferral of surgery' is the inability to reliably identify and monitor responders. In our study 'fair' Kappa agreements of 0.25, 0.26 and 0.35 were reported for ypT stage, ypN stage and ypAJCC grade respectively with understaging occurred in over 10% of cases and overstaging in over 30% of cases. These Kappa agreements exceed published agreements for other methods of assessing response such as mrRECIST [*Response Evaluation Criteria In Solid Tumors*] criteria and MR volumetric analysis (Kappa 0.12 and 0.36 respectively) [36]. However higher Kappa agreement scores of >0.4 have been reported for ymr versus pT stage assessment in selected centres [36]. Nevertheless, these data suggests that ~~in a~~ the techniques used in a typical international surgical unit for post-treatment MRI staging are~~is~~ insufficiently reliable to allow for the safe delivery of deferral of surgery.

In selected centres, multidisciplanry team (MDT) orientated standardised protocols have contributed to significant improvements in the interpretation of ~~imaging modalities~~response to chemoradiotherapy; ~~have been achieved, whereby~~ multimodal assessment, which ~~of the response of the primary tumour~~includes clincal and endoscopic examinations, are ~~is~~ performed and T2-~~with~~ MRI usually serves as the primary screening tool in the assessment of response [3~~6~~-3~~8~~]. This suggests that with optimal training and experience, current tools can be used effectively to select patients whose tumours have responded favourably to chemoradiotherapy. N~~n~~evertheless in a global setting we share the view of the authors of the MERRION study [40~~39~~] and Putte et al who suggested current imaging modalities have a low~~the poor~~ accuracy ~~of current imaging modalities for~~to predicting a true pathological complete response, ~~suggest~~ indicating that ~~this strategy~~deferral of surgery should not be offered outside of well-designed ~~controlled~~ clincal trial~~s~~s [4~~0~~1].

The actively recruiting TRIGGER randomised control trial is testing methods to identify, and safely monitor, clinical complete responders [421]. The trial identifies clinical complete responders by applying a 5-point MRI tumour regression grade (mrTRG), which most closely resembles the Mandard pathologic pTRG system [398]. The basic principle of both grading systems relate to the ratio of tumour to fibrosis following CRT. This is the first imaging technique that has been shown to assess the degree of tumour regression and to correlate the findings with pathology and with long-term survival [376, 432]. A unique aspect of this trial is that participating units are trained to report mrTRG and may only take part when the unit radiologist completes a training dataset for mrTRG and achieves a high degree of agreement with the index radiologist (Kappa ≥ 0.7) [421]. This trial may enable the dissemination of a standardised, reliable, evidence based techniques for assessing post-chemoradiotherapy response.

There are a number of limitations with this study. There is a lack of detail in terms of treatment approach. We did not know the exact radiotherapy dose used, whether pre-operative 'consolidation' or 'induction' systemic chemotherapy was used in addition to CRT or the standard waiting time between completion of CRT (or short course radiotherapy) and surgery. Consequently we have not been able to perform a multivariate analysis to explore the key risk factors for predicting a favourable response to CRT. Although it was compulsory for data to be reviewed by a senior member of the department prior to submission, no external audit of the radiology or pathology was performed and we could not be certain that recogised standardised methods were performed [34,42]. For the purposes of this study we believe this to be acceptable because it simply reflects the 'real-world' data that we aimed to assess. Finally, only patients undergoing surgery were included in the study. It is possible that a number of units already practice deferral of surgery. However, for the reasons outlined above we would recommend that this is performed within the context of a clinical trial.

Conclusions

The pathological complete response (pCR) rate of 10% reported in this international audit is consistent with rates reported in clinical trials that used concomitant chemoradiotherapy. This highlights the potential for non-operative management in selected rectal cancer patients, however the number of eligible patients may be increased if treatment strategies that enhance the overall response rate are pursued. The second barrier to non-operative management is the limited strength of agreement between post-CRT imaging and pathology. This suggests that assessing response with crude measures such as post-treatment T stage and post-treatment AJCC grade are not reliable or generalisable. Alternative detection methods, such as mrTRG with serial assessment, need to be considered in the context of clinical trials in order to feasibly allow ~~feasible and~~ safe widespread uptake of deferral of surgery.

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Authorship list (PubMed citable)

Writing group

Nick Battersby (Chair), James C. Glasbey, Peter Neary, Ionut Negoi, Sivesh Kamarajah, Alessandro Sgro, Aneel Bhangu, Thomas Pinkney, Matteo Frasson

ESCP Cohort Studies and Audits Committee

Alaa El-Hussuna (2017 Audit Lead), Nick J. Battersby, Aneel Bhangu, Nicholas C. Buchs, Christianne Buskens, Sanjay Chaudri, Matteo Frasson, Gaetano Gallo, James Glasbey, Ana María Minaya-Bravo, Dion Morton, Ionut Negoi, Dmitri Nepogodiev, Francesco Pata, Luis Sánchez-Guillén, Baljit Singh, Oded Zmora, Thomas Pinkney (Chair)

Statistical Analysis and Data Management

James Glasbey, Dmitri Nepogodiev, Rita Perry, Laura Magill, Aneel Bhangu (Guarantor)

ESCP Research Committee

Dion Morton (Chair), Donato Altomare, Willem Bemelman, Steven Brown, Christianne Buskens Quentin Denost, Charles Knowles, Søren Laurberg, Jérémie H. Lefeèvre, Gabriela Möeslein, Tom Pinkney, Carolynne Vaizey, Oded Zmora

Collaborators

Albania: S. Bilali, V. Bilali (University Hospital Center Mother Teresa).

Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron Uriburu, H. Ruiz (Buenos Aires British Hospital); P. Farina, F. Carballo, S. Guckenheimer (Hospital Pirovano).

Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. E. Theodore (Redcliffe Hospital).

Austria: F. Herbst, T. Birsan, B. Dauser, S. Ghaffari, N. Hartig (Barmherzige Brueder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg).

Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniahina (Minsk Regional Clinical Hospital).

Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaile, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Pletinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelares Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).

Bosnia and Heregovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).

Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Tercioti Jr (Hospital Centro Médico de Campinas).

Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital - First Surgery); S. Maslyankov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital, Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical

Institute - Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital - Eurohospital).

Croatia: G. Šantak, J. Ćosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).
Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Paral, O. Sotona (Charles University Hospital). M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Centrer Novy Jicin, Surgical Department); Z. Kala, M. Farkašová, T. Grolich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El-Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H-C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckmann, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn Cho Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. El Nakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awny, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University

Hospital); M. Hyöty, E. Haukijärvi, S-M. Kotaluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J. C. Etienne, E. Ghilles, B. Vinson-Bonnet (Centre Hospitalier Poissy Saint Germain en Laye~~CHIPS~~); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier (Hopital Haut Leveque); E. Tiret, N. Chafai, J. H. Lefevre, Y. Parc (Hôpital Saint-Antoine); I. Sielezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).

Greece: I. Papaconstantinou , A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta-InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, C. Chouliaras, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. E. Katsoulis, D. Balalis, D. P. Korkolis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka, I. Tóth (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis

University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbala Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saftics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Q. Parray (Sher-i-Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El-Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Moscovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Raguan, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, Y. Edden, G. Halfteck, P. Reissman~~, E. Yair~~ (Shaare Zedek ~~Mount Sinai~~Medical Center); Y. Edden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST - Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst-Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda

Ospedaliero Universitaria Consorziale Policlinico di Bari); R. Balestri, P. Buccianti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauretta, C. Belluco (Chirurgia Oncologica Generale, IRCCS Centro di Riferimento Oncologico, Aviano~~Centro di Riferimento Oncologico, IRCCS, Aviano~~); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Division of Colorectal Surgery, Department of Abdominal Surgery, Istituto Nazionale Tumori "Fondazione G.Pascale ", IRCCS Naples~~Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori~~); G. Gallo, G. Clerico, S. Cornaglia, A. Realis Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N. Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS San Raffaele, Department of Gastrointestinal Surgery~~IRCCS Ospedale San Raffaele~~); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (Policlinico~~IRCCS~~ San Martino, Genoa ~~IST~~); F. Marino, D. Lorusso, F. Pezzolla (Dept. of General Surgery, IRCCS "Saverio de Bellis", Castellana Grotte (Ba)~~IRCCS 'Saverio de Bellis'~~); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (Surgical Oncology Istituto Nazionale Tumori G.Pascale ~~National Cancer Institute~~ Naples); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa d~~D~~ei Fiori Acerra); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Podda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Ceretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti,

L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Cocorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola-Malpighi, Universita degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzon, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bauce, A. Benevento, C. Bottini, P. R. Crapa (Sant' Antonio Abate Hospital, Gallarate); M. Rubbini, G. Anania, P. Carcoforo, G. Cavallesco, C. Feo (University Hospital of Ferrara).

Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).

Latvia: A. Sivins, G. Ancans, S. Gerkis, R. Lunis, A. Pcolkins (Latvia Oncology Center).

Lithuania: D. Venskutonis, S. Bradulskis, E. Dainius, A. Subocius, J. Vencius (Deparment of General Surgery, LSMU, Kaunas Clinical Hospital); P. Zeromskas, V. Eismontas, V. Nutautiene, D. Simcikas, A. Tamosiunas (Klaipeda University Hospital); S. Svagzdys, T. Latkauskas, P. Lizdenis, Z. Saladzinskas, A. Tamelis (Lithuanian University of Health Sciences Hospital Kauno Klinikos); A. Dulskas, J. Kuliavas, N. E. Samalavicius (National Cancer Institute, Lithuania); T. Poskus, V. Jotautas, S. Mikalauskas, E. Poskus, K. Strupas (Vilnius University).

Malaysia: A. D. Zakaria, N. N.Lah, M. Wong, W. Z. Zain, Z. Zakaria (Department of Surgery, School of Medical Sciences, ~~Hospital~~ Universiti Sains Malaysia / Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).

Malta: J. Psaila, P. Andrejevic, C. Cini, S. Ellul, K. Pace (Mater Dei Hospital). Morocco: M. Ahallat, M. Hamid, A. Hrora, M. A. Majbar, M. Raiss (Ibn Sina University Hospital).

Netherlands: E. Westerduin, W. Bemelman, C. Buskens, P. Tanis (Academic Medical Centre); P.C. van der Sluis, P.H. Davids, A. Pronk, A.H.W. Schiphorst, N. Smakman (Diakonessenhuis); D. Zimmerman, T. Koeter, J. Stijns, Y-T. van Loon (Elisabeth TweeSteden Hospital); M. Vermaas, E. de Graaf, P. Doornebosch, P. van Hagen, O. van Ruler (Ijsselland Ziekenhuis); B. Toorenvliet, J. Nonner, I. van den Berg, L. van Steensel, W. Vles (Ikazia); J. Melenhorst, R. Orsini, R. Visschers (Maastricht University Medical Centre); C. Hoff (Medical Center Leeuwarden); R. Blom, H. Marsman (Onze Lieve Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Beverwijk); A. van Geloven, J. de Groof, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E. G.~~J~~. Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).

Norway: D. Ignjatovic, R. Breuer, B. Gurpreet, T. Oresland, T. Tetens Moe (Akershus University Hospital); A. Nesbakken, I. Flaaten~~h~~ Backe, T-A. Wik (Oslo University Hospital); K. Radiya, T. Dehli, P. Gjessing, S. Norderval, K. Woll (University Hospital of North Norway).

Pakistan: M. Anwer, M. S. Qureshi (JPMC WARD 2); A. U. Qureshi, M. Billah, M. Y. Jawad, A. Raza, N. Urooj (King Edward Medical University/Mayo Hospital, Lahore).

People's Republic of China: X. Wang, L. Li (West China Hospital in Sichuan University). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Czarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).

Portugal: P. Silva, A. Duarte, D. Gonçalves, M. Morais (Centro Hospitalar de S. João); N. Rama, J. Nobre, I. Sales (Centro Hospitalar Leiria, EPE); J. Costa Pereira, S. Costa, C. Costa Pereira, C. Insua, I. Romero (Centro Hospitalar Tâmega e Sousa); N. Figueiredo, J. Cunha, H. Domingos, P. Vieira (Champalimaud Foundation); M. Cunha, M. Americano, E. Amorim, J. Rachadell (Cirurgia 2 - CHA - Unidade Portimão); J. M. Carvas, I. Armas, P. Fernandes, C. Pires, R. Reis (Hospital de Bragança); R. Martins, M. Dos Santos, P. Henriques (Hospital de Faro, Centro Hospitalar do Algarve); O. Oliveira, M. Duarte, L. Ferreira, J. Miranda, N. Vilela (Hospital Distrital de Santarém, E.P.E.); J. Corte Real, S. Carlos, M. Frois Borges, P. Moniz Pereira, J. Simões (Hospital Garcia de Orta); P. Silva-vaz, V. Bettencourt, A. Gouveia, H. Perez, R. Rainho (Unidade Local de Saúde de Castelo Branco).
Romania: V. Bintintan, C. Ciuce, G. Dindelegan, R. Scurtu, R. Seicean (Clinica Chirurgie I); D. Cristian, T. Burcos, F. Grama, D. M. Mandi, G. Richiteanu (Coltea Clinical Hospital); A. Miron, V. Calu, O. Enciu, M. Nadragea, R. Parvuletu (Elias Emergency Hospital); S. S. Mogoanta, A. Crafciuc, S. Paitici (Emergency County Hospital of Craiova); I. Negoi, M. Beuran, C. Ciubotaru, A. Prodan, M. Vartic (Emergency Hospital of Bucharest); V. Tomulescu, C. Copaescu (Ponderas Academic Hospital).

Russia: A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (FSBEI HE PRMU MOH); ~~D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (City Hospital 9); A.~~ Pozdnyakov, D. Cherdancev, D. Mahotin, A. Nesytykh, V. Samsonyuk (Krasnoyarsk Regional

Clinical Hospital); I. Pravosudov, D. Ivlev, A. Karachun, K. Lebedev, D. Samsonov (N.N. Petrov National Medical Research ~~Institute~~ Center of Oncology); ~~R. Aiupov, D. Feoktistov, M. Garipov, S. Nail, N. Tarasov (National Republic Oncology Center); A. Yanishev, A. Abelevich, A. Kokobelyan, M. Lebedeva, R. Luzan (Nizhny Novgorod Regional Clinical Hospital);~~ R. Aiupov, D. Feoktistov, M. Garipov, N. Suleymanov, N. Tarasov (Republican Oncological Centre, Ufa); A. Rasulov, H. Dzhumabaev, Z. Mamedli (Russian Cancer Research Center); A. Bedzhanyan (Russian Research Center of Surgery named after B.V.Petrovsky); D. Popov, A. Sednev, A. Klimenko, A. Semenov, S. Vasilyev (Saint-Petersburg City Hospital 9); A. Khazov, M. Khanevich, G. Khrykov (Saint-Petersburg Clinical Oncological Health Center); S. Katorkin, P. Andreev, A. Chernov, O. Davidova, A. Zhuravlev (Samara State Medical University); S. Achkasov, D. Shakhmatov, Y. Shelygin, O. Sushkov, A. Vardanyan (State Scientific Centre of Coloproctology); A. Ilkanich, N. Barbashinov, V. Darvin, S. Onishchenko, Y. Voronin (Surgut District Hospital).

Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery-First~~I~~ Surgical Clinic, Clinical Center of Serbia, University of Belgrade, Medical Faculty); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D. Dabic, B. Maric, V. Perunicic (General Hospital Cacak); Z. Radovanovic, M. Djuric, D. Lukic, D. Radovanovic (Oncology Institute of Vojvodina); V. Cuk, V. Cuk, J. Juloski, M. Kenic, I. Krdzic (Surgical Clinic KBC Zvezdara).

Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Norcic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Consorci Sanitari de Terrassa - Hospital de Terrassa); J. C. Bernal-Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consorcio Hospital General Universitario); J-M. García-González, J. Cervera-Aldama, J. Ramos-Prada, M. Santamaría-Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enrriquez-Navascués, Y. Saralegui (Donostia Universitary Hospital); A. Calero-Lillo, S. Aznar-Puig, M. A. López-Lara, S. Muñoz-Collado, J. Valverde-Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez Ortega Hospital); N. Truan, R. Baldonedo, D. Fernández-Martínez~~Martínez~~, J. Otero, L. Solar-García (Hospital Universitario Central de Asturias); V. Turrado-Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de Laspra, E. Echazarreta Gallego, M. Elia Guedea (Hospital Clinico Universitario de Zaragoza); D. Escola, S. Martinez (Hospital Comarcal Alt Penedes); V. Primo Romaguera, R. Parreño, L. Pastor, E. Rosell (Hospital de Dénia); R. Lozoya Trujillo, R. Alós Company, M. D. Ruiz Carmona, A. Solana Bueno (Hospital de Sagunto); S. Salvans Ruiz, S. Alonso Gonçalves, M. Jiménez- Toscano, M. Pascual Damieta, M. Pera Roman (Hospital Del Mar); E. M. Pellicer-Franco, J. A. Garcia-Marin, M. Mengual-Ballester, V. Soria-Aledo, G. Valero-Navarro (Hospital Morales Meseguer); M. Vicente-Ruiz, C. Garcia-Zamora, A. Gonzalez-Gil, M. J. Montoya-Tabares, M. Paredes-Quiles (Hospital Rafael

Mendez); J. Die Trill, P. Abadia, I. Moreno, J. D. Pina, D. Ramos Rubio (Hospital Ramon y Cajal); J. Escartin, J. L. Blas, J. Fernando, R. Ferrer, J. Garcia Egea (Hospital Royo Villanova); I. Pros, W. Martinez, J. Rius, M. Socías (Hospital Sant Joan de Deu de Martorell); D. Sabia, J. Castellvi Valls, V. Gonzalez Santin, S. Mompart Garcia, L. Viso Pons (Hospital Sant Joan Despí Moises Broggi); D. Julià, A. Codina-Cazador, R. Farrés, N. Gómez, P. Planellas (Hospital Universitari de Girona Doctor Josep Trueta); M. Cuadrado, I. Camps (Hospital Universitari Germans Trias I Pujol); M. Rufas, J. Escoll, A. Fermiñán, P. Muriel, E. Sierra (Hospital Universitario Arnau de Vilanova de Lerida); C. Alvarez-Laso, P. Lora, H. Padin (Hospital Universitario de Cabueñes); J. Garcia-Septiem, C. Bustamante, V. Jimenez, J. Jimenez-Miramon, J. L. Ramos (Hospital Universitario de Getafe); A. B. Gallardo, P. Benito, L. Colao, P. Galindo, C. Garcia (Hospital Universitario de Torrejón de Ardoz); A. Forero-Torres, A. Alonso Poza, B. Dieguez Fernandez, C. Gilsanz Martin, M. Hernandez Garcia (Hospital Universitario del Sureste); J. A. Rojo López, J. M. Gil López, M. González Zunzárren, J. Martínez Alegre, L~~J~~. P. Zorrilla Matilla (Hospital Universitario Infanta Sofia); A. Navarro-Sánchez, F. J. Alcalá Serrano, J. López-Fernández, D. Montesdeoca Cabrera (Hospital Universitario Insular de Gran Canaria); M. Alvarez-Gallego, J. Guevara, I. Pascual Miguelañez, I. Rubio-Perez (Hospital Universitario La Paz); M. Gomez Ruiz, J. Alonso Martín, C. Cagigas Fernández, J. Castillo Diego (Hospital Universitario Marques de Valdecilla); J. A. Pando, C. Maristany, A. Muñoz-Duyos, A. Rada-Palomino, H. Vargas-Pierola (Hospital Universitario Mutua Terrassa); E. Peña Ros, J. A. Benavides Buleje, J. M. Muñoz Camarena, P. A. Parra Baños, M. Ramirez Faraco (Hospital Universitario Reina Sofía); J. J. Arenal, M. A. Citores, J. L. Marcos, J. Sánchez, C. Tinoco (Hospital Universitario Río Hortega); L. J. García Flórez, R. D. Arias Pacheco, G. Mínguez Ruiz, N. Gutiérrez~~Rodríguez~~ Corral, A. Rodríguez Infante (Hospital Universitario San Agustín); M. J. Carrillo López, M. M. Carrasco Prats, A. Lage Laredo, Á. Martínez Manzano, P. Rodríguez García (Hospital Universitario Santa Lucia); J. J. Segura-Sampedro, N. Alonso-Hernández, M. Fernandez Isart, M. Gamundi Cuesta, A. Ochogavia Segui (Hospital

Universitario Son Espases); N. Ibañez, J. Abrisqueta, J. Lujan (Hospital Universitario Virgen de la Arrixaca); R. Gómez Pérez, E. Corrales Valero, C. Monje Salazar, E. Sanchiz Cardenas, R. Soler Humanes (Hospital Universitario Virgen de la Victoria); R. M. Jimenez-Rodriguez, F. De la Portilla, J. M. Diaz Pavon, A. M. Garcia Cabrera, M. L. Reyes Diaz (Hospital Universitario Virgen del Rocio); E. Espin, F. Marinello, M. Martí, J. L. Sanchez, F. Vallribera (Hospital Valle de Hebron); F. J. Orts Mico, M. Ortin Navarro, M. Perez Climent, C. Serra Diaz (Hospital Virgen de los Lirios); M. Millan, A. Caro, J. Escuder, B. Espina, F. Feliu (Joan XXIII University Hospital); A. Climent Aira, A. Estévez Diz, M. T. Moreno Asencio, A. Varela Mato, R. Vázquez Bouzán (POVISA Hospital); A. M. Minaya-Bravo, M.M. Diez-Alonso, R. Villeta-Plaza (Principe de Asturias Hospital); H. Guadalajara, D. Alías, D. García Olmo, C. Pastor, I. Valverde (Quironsalud Publicos); A. Sanchez Romero, A. Gardea, M. Gil Santos, T. Nimmersgern, P. Serrano Paz (Unidad de Coloproctorlogia, Hospital Vinalopó-Torrevieja); M. Romero-Simó, T. Blasco-Segura, I. Caravaca-García, D. Costa-Navarro, A. Zarco-Pleguezuelos (University General Hospital of Alicante); L. Sánchez-Guillén, B. Flor-Lorente, M. Frasson, Á. García-Granero, E. García-Granero (University Hospital La Fe Valencia); B. Arencibia, J. Alonso, G. Febles, E. M. Nogués, C. Roque (University Hospital of Gran Canaria Dr. Negrín).

Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nestler (Falu lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M-L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrkoping).

Switzerland: M. Adamina, C. Freil-Lanter, C. Gingert, P. Müller, J. Schäfli (Kantonsspital Winterthur); L. Regusci, M. Brenna, F. Fasolini (Regional Hospital Mendrisio); H. Misteli, P. Kirchhoff, D. Oertli (University Hospital Basel, Switzerland); D. Hahnloser, D. Clerc, M. Hübner

(University Hospital of Lausanne, CHUV); F. Ris, N. C. Buchs, M. Chevallay, P. Morel, B. Schiltz (University Hospitals Geneva).

Taiwan: J. Y. Wang, W-C. Su, C-W. Huang, C-J. Ma, H-L. Tsai (Kaohsiung Medical University Hospital).

Turkey: ~~G. S. Özbalcı, B. B. Özkan, U. Karabacak (19 Mayis University Faculty of Medicine);~~ D. Bugra (American Hospital); F. Agalar, H. Baloglu, I. Basoglu (Anadolu Medical Center [in aff with Johns Hopkins Med]); N. Okkabaz, E. Binboga, A. Biricik, A. Celik, E. Yavuz (Bagcilar Training and Research Hospital); A. E. Canda, C. Agalar, M. Fuzun, S. Sokmen, C. Terzi (Dokuz Eylul University); A. Isik (Erzincan University, Mengucek Gazi Training and Research Hospital); B. Karip, A. C. Bilgili (Fatih Sultan Mehmet Training and Research Hospital); S. Leventoğlu, B. Aytac, E. Küçükdiler, A. Yıldız, O. Yuksel (Gazi University Medical School); H. Sinan, O. Hancerliogullari, S. Kaymak, O. Kozak, M. T. Ozer (Gulhane Training and Research Hospital); I. S. Sarici, O. Akca, M. U. Kalayci, Y. Kara (Kanuni Sultan Suleyman Training and Research Hospital); D. Bugra, O. Agcaoglu, E. Balik, O. Bayram (Koc University School of Medicine); G. S. Özbalcı, B. B. Özkan, U. Karabacak (On Dokuz Mayis University Faculty of Medicine); U. Sungurtekin, U. Ozgen (Pamukkale University School of Medicine); S. Demirbas (TOBB-ETU University Hospital); E. Öztürk, O. Isik, T. Yilmazlar (Uludag University School of Medicine); E. Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. J. Battersby, J. Broadhurst, ~~A. Mehta~~S. Moran, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington

(Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slesser (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar-Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh-Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira-Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M. Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morriston Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R. Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); ~~S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust);~~ J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Drami, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayral, A.

Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symankewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger , C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon-Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (University Hospitals Plymouth NHS Trust); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).

Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).

United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).~~ESCP Cohort Studies and Audits Committee~~

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Alaa El-Hussuna (2017 Audit Lead), Aneel Bhangu, Nicholas Buchs, Christianne Buskens, Sanjay Chaudri, Matteo Frasson, Gaetano Gallo, James Glasbey, Ana Minaya, Dion Morton, Ionut Negoi, Dmitri Nepogodiev, Francesco Pata, Luis Sánchez Guillén, Baljit Singh, Oded Zmora, Thomas Pinkney (Chair)

Statistical Analysis and Data Management

James Glasbey, Dmitri Nepogodiev, Rita Perry, Laura Magill, Aneel Bhangu (Guarantor)

ESCP Research Committee

Dion Morton (Chair), Donato Altomare, Willem Bemelman, Steven Brown, Christianne Buskens Quentin Denost, Charles Knowles, Søren Laurberg, Jérémie Lefèvre, Gabriela Möeslein, Tom Pinkney, Carolynne Vaizey, Oded Zmora

Collaborators

Albania: S. Bilali, V. Bilali (University Hospital Center Mother Teresa).

Argentina: M. Salomon, M. Cillo, D. Estefania, J. Patron Uriburu, H. Ruiz (Buenos Aires British Hospital); P. Farina, F. Carballo, S. Guckenheimer (Hospital Pirovano).

Australia: D. Proud, R. Brouwer, A. Bui, B. Nguyen, P. Smart (Austin Hospital); A. Warwick, J. Theodore (Redcliffe Hospital).

Austria: F. Herbst, T. Birsan, B. Dauser, S. Ghaffari, N. Hartig (Barmherzige Brueder, Wien); A. Stift, S. Argeny, L. Unger (Medical University of Vienna); R. Strouhal, A. Heuberger (Oberndorf b. Salzburg).

~~Belarus: A. Varabei, N. Lahodzich, A. Makhmudov, L. Selniahina (Minsk Regional Clinical Hospital).~~

~~Belgium: T. Feryn, T. Leupe, L. Maes, E. Reynvoet, K. Van Langenhove (AZ Sint-Jan Brugge); M. Nachtergaele (AZ St Jozef); B. Monami, D. Francart, C. Jehaes, S. Markiewicz, J. Weerts (Clinique St Joseph, Liege); K. Van Belle, B. Bomans, V. Cavenaile, Y. Nijs, M. Vertruyen (Europe Hospitals Brussels); P. Pletinckx, D. Claeys, B. Defoort, F. Muysoms, S. Van Cleven (Maria Middelares Gent); C. Lange, K. Vindevoghel (OLV van Lourdes Hospital Waregem); A. Wolthuis (University Hospital Leuven).~~

~~Bosnia and Heregovina: M. Todorovic, S. Dabic, B. Kenjic, S. Lovric, J. Vidovic (JZU Hospital Sveti Vračevi); S. Delibegovic, Z. Mehmedovic (University Clinic Center Tuzla).~~

~~Brazil: A. Christiano, B. Lombardi, M. Marchiori Jr, V. Tercioti Jr (Hospital Centro Médico de Campinas).~~

~~Bulgaria: D. Dardanov, P. Petkov, L. Simonova, A. Yonkov, E. Zhivkov (Alexandrovska Hospital - First Surgery); S. Maslyankov, V. Pavlov, M. Sokolov, G. Todorov (Alexandrovska Hospital, Second Surgery Clinic); V. Stoyanov, I. Batashki, N. Iarumov, I. Lozev, B. Moshev (Medical Institute - Ministry of Interior); M. Slavchev, B. Atanasov, N. Belev, P. Krstev, R. Penkov (University Hospital - Eurohospital).~~

~~Croatia: G. Šantak, J. Ćosić, A. Previšić, L. Vukušić, G. Zukanović (County Hospital Požega); M. Zelić, D. Kršul, V. Lekić Vitlov, D. Mendrila (University Hospital Rijeka).~~
~~Czech Republic: J. Orhalmi, T. Dusek, O. Maly, J. Paral, O. Sotona (Charles University Hospital). M. Skrovina, V. Bencurik, M. Machackova (Complex Oncology Centrer Novy Jicin,~~

Surgical Department); Z. Kala, M. Farkašová, T. Grolich, V. Procházka (Surgical Department, University Hospital Brno); J. Hoch, P. Kocian, L. Martinek (University Hospital Motol, Prague); F. Antos, V. Pruchova (University Hospital Prague Bulovka).

Denmark: A. El Hussuna, A. Ceccotti, T. Madsbøll, D. Straarup, A. Uth Ovesen (Aalborg University Hospital); P. Christensen, P. Bondeven, P. Edling, H. Elfeki, V. Alexandrovich Gameza, S. Michelsen Bach, I. Zheltiakova (Aarhus University Hospital/Randers Regional Hospital); PM. Krarup, A. Krogh, H C. Rolff (Bispebjerg); J. Lykke, A. F. Juvik, H. H. K. Lóven, M. Marckman, J. T. F. Osterkamp (Herlev Hospital); A. H. Madsen, J. Worsøe (Hospital Unit West); A. Ugianskis (North Denmark Regional Hospital); M. D. Kjær, B. Youn Cho Lee (Odense University Hospital); A. Khalid, M. H. Kristensen (Regional Hospital Viborg).

Egypt: M. El Sorogy, A. Elgeidie, M. Elhemaly, A. ElNakeeb, M. Elrefai (Gastrointestinal Surgery Center, Mansoura University); M. Shalaby, S. Emile, W. Omar, A. Sakr, W. Thabet (Mansoura University Hospital); S. Awny, I. Metwally, B. Refky, N. Shams, M. Zuhdy (Oncology Center Mansoura University).

Finland: A. Lepistö, I. Keränen, A. Kivelä, T. Lehtonen, P. Siironen (Helsinki University Hospital); T. Rautio, M. Ahonen-Siirtola, K. Klintrup, K. Paarnio, H. Takala (Oulu University Hospital); M. Hyöty, E. Haukijärvi, S M. Kotaluoto, K. Lehto, T. Tomminen (Tampere University Hospital); H. Huhtinen, A. Carpelan, J. Karvonen, A. Rantala, P. Varpe (Turku University Hospital).

France: E. Cotte, Y. Francois, O. Glehen, G. Passot (Centre Hospitalier Lyon Sud); A. d'Alessandro, E. Chouillard, J. C. Etienne, E. Ghilles, B. Vinson Bonnet (CHIPS); A. Germain, A. Ayav, L. Bresler (CHU Nancy-Brabois); R. Chevalier, Q. Denost, R. Didailler, E. Rullier

(Hopital Haut Leveque); E. Tiret, N. Chafai, J. Lefevre, Y. Parc (Hôpital Saint-Antoine); I. Sielezneff, D. Mege (Timone Hospital); Z. Lakkis (University Hospital of Besancon); M. Barussaud (University Hospital of Poitiers).

Germany: C. Krones, B. Bock, R. Webler (Marienhospital Aachen); J. Baral, T. Lang, S. Münch, F. Pullig, M. Schön (Städtisches Klinikum Karlsruhe); S. Hinz, T. Becker, T. Möller, F. Richter, C. Schafmayer (University Hospital Schleswig-Holstein, Kiel); J. Hardt, P. Kienle (University Medical Center Mannheim); F. Crescenti, M. Ahmad, Y. Soleiman (Verden KRH).
Greece: I. Papaconstantinou , A. Gklavas, K. Nastos, T. Theodosopoulos, A. Vezakis (Areteion Hospital); K. Stamou, A. Saridaki (Athens Bioclinic); E. Xynos, S. Paraskakis, N. Zervakis (Creta-InterClinic Hospital); G. Skroubis, T. Amanatidis, S. Germanos, I. Maroulis, G. Papadopoulos (General University Hospital of Patras); N. Dimitriou, A. Alexandrou, E. Felekouras, J. Griniatsos, I. Karavokyros (Laiko Hospital); A. Papadopoulos, C. Chouliaras, P. Ioannidis, D. Katsounis, E. Kefalou (Nikaia General Hospital); I. Katsoulis, D. Balalis, D. Manatakis (St. Savvas Cancer Hospital); G. Tzovaras, I. Baloyiannis, I. Mamaloudis (University Hospital of Larissa).

Hungary: G. Lázár, S. Ábraham, A. Paszt, Z. Simonka (Department of Surgery, University of Szeged); A. Zaránd, Z. Baranyai, G. Ferreira, L. Harsányi, P. Ónody (Semmelweis University, 1st Clinic of Surgery); B. Banky, Á. Burány, M. Lakatos, J. Marton, A. Solymosi (St. Borbala Hospital); I. Besznyák, A. Bursics, G. Papp, G. Saftics, I. Svastics (Uzsoki Hospital);

Iceland: E. Valsdottir, J. Atladottir, T. Jonsson, P. Moller, H. Sigurdsson (University Hospital of Iceland).

India: S. K. Gupta, S. Gupta, N. Kaul, S. Mohan, G. Sharma (Government Medical College, Jammu, Jammu and Kashmir, India); R. Wani, N. Chowdri, M. Khan, A. Mehraj, F. Parray (Sher-i Kashmir Institute of Medical Sciences).

Ireland: A. Coveney, J. Burke, J. Deasy, S. El Masry, D. McNamara (Beaumont Hospital); M. F. Khan, R. Cahill, E. Faul, J. Mulsow, C. Shields (Mater Misericordiae University Hospital); M. E. Kelly, G. Bass, S. T. Martin, R. O'Connell, E. Ryan (St Vincent's Private Hospital); T. Connelly, G. Ahmad, W. Bukhari, F. Cooke (University Hospital Waterford).

Israel: O. Zmora, R. Gold Deutch, N. Haim, R. Lavy, A. Moscovici (Assaf Harofe Medical Center); N. Shussman, R. Gefen, G. Marom, A. Pikarsky, D. Weiss (Hadassah Hebrew University Medical Center); S. Avital, N. Hermann, B. Raguan, M. Slavin, I. White (Meir Medical Center); N. Wasserberg, H. Arieli, N. Gurevich (RMC, Beilinson Campus); M. R. Freund, S. Dorot, G. Halfteck, P. Reissman, E. Yair (Shaare Zedek Mount Sinai); Y. Eden, R. Pery (Sheba Medical Center); H. Tulchinsky, A. Weizman (Sourasky Medical Center).

Italy: F. Agresta, R. Curinga, E. Finotti, G. Savino, L. A. Verza (Adria Hospital); C. R. Asteria, L. Boccia, A. Pascariello (ASST - Mantua); N. Tamini, A. Bugatti, L. Gianotti, M. Totis (Asst-Monza, Ospedale San Gerardo); L. Vincenti, V. Andriola, I. Giannini, E. Travaglio (Azienda Ospedaliero Universitaria Consorziale Policlinico di Bari); R. Balestri, P. Buccianti, N. Roffi, E. Rossi, L. Urbani (Azienda Ospedaliero Universitaria Pisana); A. Mellano, A. Cinquegrana (Candiolo Cancer Institute IRCCS); A. Lauretta, C. Belluco (Centro di Riferimento Oncologico, IRCCS, Aviano); M. Mistrangelo, M. E. Allaix, S. Arolfo, M. Morino, V. Testa (Citta della Salute e della Scienza di Torino); P. Delrio, U. Pace, D. Rega, D. Scala (Colorectal Surgical Oncology Istituto Nazionale per lo Studio e la Cura dei Tumori); G. Gallo, G. Clerico, S. Cornaglia, A. Realis Luc, M. Trompetto (Department of Colorectal Surgery, S. Rita Clinic); G. Ugolini, N.

Antonacci, S. Fabbri, I. Montroni, D. Zattoni (Faenza Hospital); C. D'Urbano, A. Cornelli, M. Viti (G. Salvini); M. Inama, M. Bacchion, A. Casaril, H. Impellizzeri, G. Moretto (Hospital Dott. Pederzoli); A. Spinelli, M. Carvello, G. David, F. Di Candido, M. Sacchi (Humanitas Research Hospital); A. Frontali, V. Ceriani, M. Molteni (IRCCS MultiMedica); R. Rosati, F. Aleotti, U. Elmore, M. Lemma, A. Vignali (IRCCS Ospedale San Raffaele); S. Scabini, G. Casoni Pattacini, A. Luzzi, E. Romairone (IRCCS San Martino IST); F. Marino, D. Lorusso, F. Pezzolla (IRCCS 'Saverio de Bellis'); F. Colombo, C. Baldi, D. Foschi, G. Sampietro, L. Sorrentino (L. Sacco University Hospital); S. Di Saverio, A. Birindelli, E. Segalini, D. Spacca (Maggiore Hospital); G. M. Romano, A. Belli, F. Bianco, S. De franciscis, A. Falato (National Cancer Institute Naples); A. Muratore, P. Marsanic (Ospedale Agnelli Pinerolo); S. Grimaldi, N. Castaldo, M. G. Ciolli, P. Picarella, R. Porfidia (Ospedale Convenzionato Villa Dei Fiori); S. Di Saverio, A. Birindelli, G. Tugnoli (Ospedale Maggiore); A. Bondurri, D. Cavallo, A. Maffioli, A. Pertusati (Ospedale Sacco Italy); F. Pulighe, F. Balestra, C. De Nisco, M. Podda (Ospedale San Francesco); E. Opocher, M. Longhi, N. M. Mariani, N. Maroni, A. Pisani Ceretti (Ospedale San Paolo); R. Galleano, P. Aonzo, G. Curletti, L. Reggiani (Ospedale Santa Corona); M. Marconi, L. Del Prete, M. Oldani, R. Pappalardo, S. Zaccone I (Ospedale Santa Maria delle Stelle); M. Scatizzi, M. Baraghini, S. Cantafio, F. Feroci, I. Giani (Ospedale Santo Stefano, Prato); R. Tutino, G. Cocorullo, G. Gulotta, L. Licari, G. Salamone (Policlinico 'P. Giaccone'); P. Sileri, F. Saraceno (Policlinico Tor Vergata); F. La Torre, P. Chirletti, D. Coletta, G. De Toma, A. Mingoli (Policlinico Umberto I 'Sapienza University'); M. Papandrea, E. De Luca, R. Sacco, G. Sammarco, G. Vescio (Policlinico Universitario di Catanzaro); V. Tonini, S. Bianchini, M. Cervellera, S. Vaccari (Policlinico universitario Sant'Orsola Malpighi, Universita degli Studi di Bologna); N. Cracco, G. Barugola, E. Bertocchi, R. Rossini, G. Ruffo (Sacro Cuore Don Calabria Hospital); A. Sartori, N. Clemente, M. De Luca, A. De Luca, G. Scaffidi (San Valentino Hospital); L. Lorenzon, G. Balducci, T. Bocchetti, M. Ferri, P. Mercantini (Sant'Andrea Hospital); F. Pata, S. Bauce, A.

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~~Japan: T. Yamamoto (Yokkaichi Hazu Medical Centre).~~

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~~Malaysia: A. Zakaria, N. N.Lah, M. Wong, Z. Zain, Z. Zakaria (Hospital Universiti Sains Malaysia); L. Mazlan, Z. A. Mohd Azman, I. Sagap (UKM Medical Centre).~~

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~~Leeuwarden); R. Blom, H. Marsman (Onze Lieve Vrouwe Gasthuis); I. Mulder, H. Cense, S. de Castro, A. Demirkiran, M. Hunfeld (Rode Kruis Ziekenhuis Beverwijk); A. van Geloven, J. de Groof, E. Hendriks, M. Leeuwenburg, N. van Oorschot (Tergooi); F. Wit, C. Rupert, P. Veldman (Tjongerschans ziekenhuis); M. Keijzers, J. Konsten (VieCuri Medisch Centrum voor Noord Limburg); F. Den Boer, M. Corver (Zaans Medical Center); E J. Boerma, L. Koolen, M. Martens, K. Van Wijck (Zuyderland Medical Center).~~

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~~People's Republic of China: X. Wang, L. Li (West China Hospital). Poland: D. Jajtner, B. Gasinski, W. Kabiesz (Beskidian Oncology Center); P. Walega, M. Romaniszyn (Third Department of General Surgery, Jagiellonian University Medical College); M. Zawadzki, R. Czarnecki, Z. Obuszko, M. Rzaca, M. Sitarska (Wojewódzki Szpital Specjalistyczny).~~

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Serbia: Z. Krivokapić, G. Barišić, I. Dimitrijević, V. Marković, A. Sekulić (Clinic for Digestive Surgery I Surgical Clinic, Clinical Ceter of Serbia); G. Stanojevic, B. Brankovic, M. Nestorovic, V. Pecic, D. Petrovic (Clinic for General Surgery, Clinical Center Nis); I. Kostic, A. Aleksic, D.

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Singapore: J. C. Ngu, Y. Y. Ng, N. Teo (Changi General Hospital).

Slovak Republic: J. Korcek, A. Lazorisak, (Faculty Hospital Nitra).

Slovenia: M. Rems, Š. Ramovš Trampuš (General Hospital Jesenice); A. Tomazic, J. Grosek, J. Kosir, G. Norcic (University Medical Centre Ljubljana).

Spain: V. Vigorita, N. Caceres, E. Casal, A. Ruano, I. Trostchansky (Alvaro Cunqueiro Hospital); T. Golda, A. Galvez Saldaña, E. Kreisler Moreno, J. Lopez Dominguez, M. Vila Tura (Bellvitge University Hospital); F. Labarga, P. Galvez, V. Maderuelo, C. Suero (Complejo Asistencial Universitario de Palencia); J. Bargallo, L. Cayetano, S. Lamas, M. C. Silva (Consorci Sanitari de Terrassa - Hospital de Terrassa); J. C. Bernal-Sprekelsen, R. Gómez, S. Jareño, A. Ríos, D. Vercher (Consorcio Hospital General Universitario); J-M. García-González, J. Cervera-Aldama, J. Ramos Prada, M. Santamaría Olabarrieta (Cruces University Hospital); N. Borda, J. M. Enrriquez-Navascués, Y. Saralegui (Donostia Universitary Hospital); A. Calero-Lillo, S. Aznar-Puig, M. A. López Lara, S. Muñoz Collado, J. Valverde Sintas (Fundacio Hospital Esperit Sant); P. Menendez, C. Leon (Gutierrez Ortega Hospital); N. Truan, R. Baldonedo, D. Martínez, J. Otero, L. Solar (Hospital Central de Asturias); V. Turrado Rodriguez, F. de Lacy Oliver, A. M. Lacy Fortuny, B. Martin Perez, A. M. Otero Piñeiro (Hospital Clinic Barcelona); J. Paredes, F. Fernandez, M. J. Ladra, A. Paulos, D. Prieto (Hospital Clinico Universitario de Santiago de Compostela); J. P. Beltrán de Heredia, F. Blanco Antona, B. de Andrés Asenjo, C. Ferreras García, A. Romero de Diego (Hospital Clínico Universitario de Valladolid); E. Cordoba Diaz de

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Sweden: J. Segelman, J. Nygren (Ersta Hospital); G. Nestler (Falu lasarett); M. Abraham-Nordling, M. Egenvall (Karolinska University Hospital); P. Myrelid, B. Jung, P. Loftås (Linköping University Hospital); M-L. Lydrup, N. Azahr, P. Buchwald, P. Mangell, I. Syk (Skane University Hospital); M. Nikberg, J. Carlander, A. Chabok, K. Smedh, C. Tiselius (Västmanlands Hospital Västerås); S. Haapaniemi, A. Benckert (Vrinnevi Hospital Norrkoping).

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Taiwan: J. Y. Wang, W-C. Su, C-W. Huang, C-J. Ma, H-L. Tsai (Kaohsiung Medical University Hospital).

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Colak, S. Karagul, V. Kinas (University of Health Sciences, Samsun Training and Research Hospital).

UK: N. Fearnhead, I. Lord, P. Stewart (Addenbrooke's [Cambridge University] Hospital); M. Zammit (Basildon Hospital); S. Arnold, N. Battersby, J. Broadhurst, A. Mehta, F. Seretis (Basingstoke and North Hampshire Hospital); J. Shabbir, C. Jones, J. Kynaston (Bristol Royal Infirmary); D. Vimalachandran, E. Blower, C. McFaul, D. McWhirter, J. Pilkington (Countess of Chester Hospital); T. Wilson, M. Chowdhary (Doncaster Royal Infirmary); B. Stubbs, M. Abdalkoddus, C. Lai, N. Thavanesan, C. Yao (Dorset County Hospital); T. Agarwal, S. Dindyal, R. M. C. Hill, S. Reade, A. Slesser (Ealing Hospital); H. Paterson, A. Balfour, M. Boland, A. Geraghty, J. O'Kelly (Edinburgh Western General Hospital); P. Patel, S. Tezas (Furness General Hospital); S. Yahia, V. Jadhav, K. Marimuthu, A. Narayanan, B. Piramanayagam (George Eliot Hospital); N. Bradley, F. Buchanan, K. Paul, J. Singh, K. Thomson (Glasgow Royal Infirmary); S. Korsgen, M. Bedford, K. Lee, K. Leong (Good Hope Hospital); D. McArthur, A. Bhangu, S. Malik, I. Mohamed (Heartlands Hospital); P. Cunha, A. Pilavas (Homerton University Hospital NHS Trust); A. Reddy, S. Ahmed, A. Ahmed, J. Voll (James Cook University Hospital); V. Velchuru, R. Lal, B. Mirshekar-Syahkal (James Paget Hospital); M. Kassai, M. Aleem, S. Keogh Bootland (Jersey General Hospital); P. Sarmah, S. Brown, R. Keegan, A. Kelkar, P. Sen (Kettering General Hospital); M. Oliveira-Cunha, S. Chaudhri, R. Fares, B. Singh, W. M. Thomas (Leicester General Hospital); M. I. Aslam, K. Boyle, D. Hemingway, A. Miller, M. Norwood (Leicester Royal Infirmary); S. Gurjar, M. Al-Saeedi, L. Anandan, A. Sudlow, N. Zampitis (Luton & Dunstable Hospital); K. Malik, M. Bogdan, C. Smart (Macclesfield District General Hospital); M. R. Iqbal, S. Bailey, D. Lawes, G. Omar, R. Tamhane (Maidstone and Tunbridge Wells NHS Trust); M. Evans, S. Ather, J. Lim, H. Nageswaran, G. Taylor (Morriston Hospital); L. Hunt, J. Nicholls (Musgrove Park Hospital); I. Shaikh, F. Muscara, J. O'Brien, E. Photi, A. Stearns (Norfolk and Norwich University Hospital); D. Meylemans, C. Cunningham, R.

Hompes (Oxford University Hospitals); A. Tennakoon, N. Kumarasinghe, M. Rao, I. Upanishad (Pilgrim Hospital); S. Smolarek, E. Platt, B. Rossi, J. C. Tham (Plymouth Hospital NHS Trust); J. Khan, N. Ahmad, Z. Shweejawee, S. Stefan (Queen Alexandra Hospital); N. Smart, I. Daniels, T. Gregoir, L. Longstaff, F. McDermott (Royal Devon & Exeter Hospital); M. Varcada, I. Drami, T. Gala, E. Moggia, K. Ratnatunga (Royal Free Hospital NHS Trust Hampstead); R. Harries, J. Hayes, G. Williams (Royal Gwent Hospital); T. Raymond, C. Bronder, E. Davies, P. Hawkin, O. Ryska (Royal Lancaster Infirmary); K. Ayral, A. Beveridge, A. Bhowmik, M. Gill, R. Simpson (Royal Preston Hospital); A. Schofield, K. McArdle, M. Parmar (Royal Shrewsbury Hospital); M. Williamson, H. Burton, E. Courtney, C. Grant, A. Saracino (Royal United Hospital Bath); K. Newton, J. Epstein (Salford Royal NHS Foundation Trust); G. Branagan, M. Bignell, M. Symankewicz (Salisbury District Hospital); S. Zaman, R. Mankotia, Z. Siddiqui, A. Torrance (Sandwell General Hospital); D. Artioukh, M. Eggleston, K. Gokul, D. Selwyn (Southport and Ormskirk Hospitals); J. Warusavitarne, P. Chandrasinghe, J. Grainger , C. A. Leo, C. J. Vaizey (St Mark's Hospital); G. Harris, B. Levy, A. Skull (St Richard's Hospital); M. Thaha, S. Ahmed, A. Garg, H. Patel, A. Ramsanahie (The Royal London Hospital, Barts Health NHS Trust); M. Mondragon-Pritchard, K. Cuinas Leon, G. Williams (The Royal Wolverhampton NHS Trust); A. Shukla, H. Brewer, J. Fitzgerald, H. Kho (United Lincolnshire Hospitals NHS Trust); J. Torkington, S. Tate, J. Wheat (University Hospital of Wales); J. Knight, J. Richardson, A. Tzivanakis (University Hospital Southampton); M. Gregori, M. A. Ashraf, M. Atif, A. Birindelli, J. Santos (University Hospitals Birmingham NHS FT); N. Saffaf, M. I. Aslam, L. Canning (Warwick Hospital); N. Chandratreya, M. Bowen, B. Graham, Y. Hamad, M. Kaubrys (Weston General Hospital at Weston super Mare); Z. U. Chaudhry, C. Bhan, H. Mukhtar, A. Oshowo, J. Wilson (Whittington Hospital NHS Trust); J. Richardson, N. Gouvas, D. Nicol, S. Pandey, M. Zilvetti (Worcestershire Royal Hospital); A. Sharma, T. Fatayer, S. Mothe, M. Rahman (Wythenshawe Hospital, UHSM); N. Curtis, A. Allison, R. Dalton, N. Francis, J. Ockrim (Yeovil District Hospital).

~~Ukraine: G. Psaras, H. Dudarovaska, T. Marharint, E. Mostovoy, S. Voloshin (Mariupol Cancer Center); O. Kolesnik, D. Makhmudov (National Cancer Institute, Ukraine).~~

~~United States: Y. Altinel (Cleveland Clinic); A. Iqbal, L. Cunningham, K. Go, S. Tan (University of Florida).~~

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